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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,165	04/16/2004	Jiro Kanie	889_001	8549
25191	7590	09/24/2004	EXAMINER	
BURR & BROWN PO BOX 7068 SYRACUSE, NY 13261-7068			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 09/24/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/826,165	Applicant(s) KANIE, JIRO	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/5/04 & 4/16/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statements dated 4/16/04 and 5/05/04; Foreign Priority Paper 5/05/04

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The claims recite various limitations, which are confusing to the examiner. In claims 1 and 4, limitations regarding the shape of the enteral formulation state that the shape is retained before, during and after administration (lin. 22-25). The examiner is confused as to how this is possible when the composition must travel from the holding container, through the feeding tube and into the body. The composition would surely take the shape of the container, feeding tube during administration essentially changing its shape from that of the container to that of the tube. Clarification on this matter is required. Claims 3, recites that a mixture comprises the liquid nutrient and a semi-solidifying agent. The claims recites that heated mixture contains whole egg, while the cooled mixture contains agar as the semi-solidifying agent (lines 12-16). It is unclear to the examiner how many mixtures are present, or if the semi-solidifying agents should be referred to in the alternative. Clarification is required on these matters.

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4. The term "same hardness as ... Japanese pot-steamed hotchpotch called CHAWAN-MUSHI" in claim 1 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant has merely made a comparison to recipe yet has not given any guidance regarding specific viscosity or consistency. Since cooking is a subjective art, the texture and consistency of each individual's CHAWAN-MUSHI cannot be the same. Therefore this is an insufficient description of the claimed invention. Clarification on this matter is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Colarow et al (USPN 5,543,169 hereafter '169). The claim is drawn to an enteral nutritional composition comprising nutritional liquid and a semi-solidifying agent.

3. The '169 patent discloses protein containing food products that have stability to heat treatment (abstract). Enteral food compositions such as creams, pudding and mayonnaises are disclosed (col. 2, lin. 18 – 29). These compositions comprise water, milk and eggs (yolk and white) (col. 4, lin. 1-15). Regarding the limitation reciting the process by which the nutrient product is formed, it is the position of the examiner that these limitations do not impart

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patentability on the claim. Limitations such as this render the claims product-by-process, and are therefore examined on the merit of the product and not the process. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the claim is drawn to an enteral nutrient product which is semi-solid. The ‘169 patent discloses semi-solid emulsions which are stable under heat –treatment. These disclosures render the claim anticipated.

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ying et al (***Molded Rice Pudding with Chestnuts*** recipe entry; *The New Good Housekeeping Cookbook*, 1986, pg. 542). The claims are drawn to an enteral nutrient product and a method of production. The method comprises mixing the nutrient liquid and semi-solidifying agent in a holder other than the container and heat-treating the mixture.

5. The recipe calls for 3 whole eggs (semi-solidifying agent) to be mixed with 3 cups of milk (nutrient liquid) and other ingredients (step 2). The mixture is blended and added to another milk mixture and cooked in a saucepan (step 2). The combination is whipped and homogenized, then cooled (step 4). The product is an excellent source of calcium (nutritional information). These disclosures render the claims anticipated.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Colarow et al (USPN 5,543,169 hereafter '169), (***Molded Rice Pudding with Chestnuts*** recipe entry; *The New Good Housekeeping Cookbook*, 1986, pg. 542), Kabushiki et al (***Total Parenteral Nutritional and Enteral*** Nutrition, page 283-307, Suppl. 5, *Nippon Rinsho*, vol. 59, no. 782) and Kamarei (USPN 5,985,339 hereafter '339). The claims are drawn to an enteral nutrient product, a method for its production and an enteral device comprising the product, container and feeding tube with a diameter larger than 4 mm.

9. As discussed above the '169 patent and the Ying recipe disclose enteral products which are heat-treated and comprises semi-solidifying agents mixed with a nutrient liquid. The references however do not disclose the device containing the nutritional product.

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10. The Kabushiki reference discloses an enteral feeding method for gastric catheterization and duodenum catheterization. The device administers thick fluid diets using tubing with diameters larger than 4 mm (diagram). The reference however does not disclose heat-treatment of the nutrient composition. A skilled artisan would be motivated to use the tubing of this device in order to deliver the nutritional product since the tube would be wide enough to support and allow even flow of thicker fluid diets.

11. The '339 patent discloses nutritional drink formulation suitable for enteral tube feeding directly to the stomach, where the nutritional product comprises milk, and other protein products and must be heat-treated for sterilization (col. 9, lin. 49 – 12, lin. 11). The composition comprises whey proteins, milk, water, fats and other ingredients well known in the art (examples).

12. With these things in mind a skilled artisan would have been motivated to combine the teachings of the art. A skilled artisan would have been motivated to heat-treat the product as shown in '339 and the pudding recipe in order to kill possible harmful pathogens in the eggs or milk. A skilled artisan would have been motivated to use the wider tubing of Kabushiki in order to ensure even flow of the thicker fluid diet. A skilled artisan would have been motivated to combine these teachings into the device of '339 in order to deliver the diet directly to the stomach of a person in need thereof. It would have been obvious to a skilled artisan to combine the suggestion and teachings of the art as such with an expected result of an enteral nutritional product and device for its delivery.

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Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mulchandani et al (USPN 5,108,767), Forse et al (USPN 5,821,217) and Gray et al (USPN 5,821,217) all disclose enteral delivery of nutritional products comprising protein products.

14. All claims have been rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE, M.A., J.D.
SUPERVISORY PATENT EXAMINER